Medicare Part B Drug CAP
Responses to Questions from the December 1, 2005 Open Door Forum
December16, 2005

General Vendor Application Information

Q: Will bids that incompletely meet the application criteria be automatically rejected?

A: We invite all interested parties to submit applications. We do not plan to make exceptions or allowances for potential vendors that do not meet financial or quality criteria. However, we also appreciate that some standards may be subject to interpretation, particularly to bidding entities that are composed of several organizations. We recommend that any bidders fully and completely explain how application standards have been met in the appropriate narrative sections of the application.

CAP Drug List

Q: Will vendors be expected to bid on all HCPCS codes listed in addendum F and G of the Final Rule, even if drugs in the HCPCS code are in short supply or unavailable?

A: Yes, we expect bids on all of the listed codes. All of these codes have prices on the current ASP file. If a code is identified as unavailable during the CAP contract period, substitution procedures as described in Section 414.906 may be utilized

Q: Do the drugs listed in addenda F and G reflect the most recent policy on hyaluronan and hyaluronic acid derivatives?

A: Yes. CMS Manual transmittal 749 dated November 8, 2005 states that "CMS will not implement its decision to establish a single new code - J7318 "Hyaluronan (Sodium Hyaluronate) or Derivative, Intra-Articular Injection, 1mg" – to describe all sodium hyaluronate/hyaluronans. The codes used in 2005 will still apply." Therefore, J7317 and J7320 are valid codes for this round of CAP bidding. Orthovisc and Euflexxa are not included in this round of CAP.

Orphan Drugs

Q. Can a vendor add an orphan drug at any time or must it include the orphan in the bid?

A. Under Section 414.906(f) (2) (B) vendors are allowed to petition CMS to add certain single indication orphan drugs to their CAP drug lists. The process for making this request is outlined in Section 414.906(f)(3). Such requests do not need to be included with the vendor's initial bid. We will be issuing guidance on the process for requesting the addition of single indication orphan drugs to the approved CAP vendor's CAP drug list at a later date. We plan to act on the initial requests for

adding drugs to the approved CAP vendor's CAP drug list after the July 1, 2006 inception of the program.

Drug Ordering Process

Q: Will CMS implement a minimum order size (by dollar amount).

A: The CAP is not designed to require minimum order quantities. However, we anticipate that most physicians who elect to participate in the CAP will place CAP orders for several beneficiaries and/or several courses of treatment at one time in order to lessen the burden of ordering and receiving CAP drugs. Furthermore, the variety of drugs available through the CAP makes it more likely that a participating CAP physician can order most of a beneficiary's drug therapy through the CAP, rather than just a few select items. Therefore, we believe that the design of the program makes a minimum order size unnecessary.

We also remind bidders that the ordering and shipping process is intended to be flexible. Specifically, we note that a CAP vendor may combine shipments for more than one beneficiary at a time and may also split large shipments, provided that delivery complies with timeframes described in Sections 414.902 and 414.914 (f) of the CAP regulations.

Unused Drugs

Q: Does the policy on the unused portion of a CAP drug apply to multidose vials?

A: No, as stated on page 70248 of the November 21, 2005 CAP final rule, the CMS policy regarding payment for unused drugs applies only to single dose vials.

Q: Does the policy on the unused portion of a CAP drug described in the final rule apply to all single dose vials regardless of size?

A: The criteria for payment of the unused portion of a CAP drug is explained on page 70248 of the November 21, 2005 CAP final rule. The policy is not dependent on the size of the vial being ordered. This policy also applies to single use ampules. We consider the unused portion of a drug remaining in an opened single-use vial to be administered for the limited purpose of section 1847B(a)(3)(A)(iii)(II) of the Act, but only if the participating CAP physician has made god faith efforts to minimize the unused portion of the CAP drug in how he or she scheduled patients and how he or she ordered, accepted, stored, and used the drug, and only if the approved CAP vendor has made good faith efforts to minimize the unused portion of the drug in how it supplied the drug.

Beneficiary Issues

Q: Will agreements between physicians and CAP vendors for the collection of beneficiary coinsurance be exempt from certain Medicare laws concerning inducements?

A: No. We have made no provision for exemption from any current laws. As stated in the Final Rule, arrangements between participating CAP physicians and approved CAP vendors must not violate the physician self referral ("Stark") prohibition, the Federal anti-kickback statute, or any other Federal or State law or regulation governing billing or claims submission. We also stated in the Final Rule (70 FR 70251-2) that we would not dictate or specify the breadth or the specific obligations contained in these arrangements, other than to note that they must comply with applicable law and that the approved CAP vendor may not coerce participating CAP physicians into entering any such arrangement.

Q: Will it be necessary for a CAP vendor to obtain an Assignment of Benefits (AOB) form from beneficiaries prior to billing Medicare for drugs and biologicals shipped to CAP physician offices pursuant to a valid CAP physician order?

A: Mandatory assignment applies to Part B drugs and biologicals, see Section 1842(o)(3) of the Social Security Act; therefore, a physician or supplier does not have to obtain a signed assignment of benefits form from the beneficiary in connection with Part B drug claims. In addition, while normally the supplier would need to obtain the beneficiary's signature to file a claim, the approved CAP vendor may sign the claim form on behalf of the beneficiary pursuant to 42 CFR 424.36(c), because the CAP drug claim will involve no personal contact between the approved CAP vendor and the beneficiary.